IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TEXAS
TYLER DIVISION

NUTRITION 21, LLC,	§	
	§	
Plaintiff,	§	
	§	**CASE NO. 6:05-CV-228**
vs.	§	**PATENT CASE**
	§	
GENERAL NUTRITION CORPORATION,	§	
	§	
Defendant.	§	

MEMORANDUM OPINION

This claim construction opinion interprets disputed terms in United States Patent Nos. 5,087,623 ("the '623 Patent"), 5,087,624 ("the '624 Patent"), and 5,175,156 ("the '156 Patent") (collectively "the patents-in-suit"). Having considered the parties' submissions and oral arguments, the Court construes the terms at issue as follows.[1]

BACKGROUND

The patents-in-suit are directed to the administration of the chemical compound chromic picolinate, and preferably chromic tripicolinate,[2] as a prophylactic or therapeutic agent for controlling various blood serum parameters. Specifically, the '623 Patent is directed to methods of controlling desirable high blood serum glucose levels for the treatment of maturity-onset diabetes. The '624

[1] Appendix A to this Memorandum Opinion contains the relevant claims of the patents-in-suit, with the construed terms indicated in boldface type. Appendix B contains the Court's Claim Construction Chart, which construes the relevant terms.

[2] The parties agree that for purposes of construction both chromic picolinate and chromic tripicolinate may be abbreviated as "CP."

Patent is directed to methods of facilitating uptake of amino acids by skeletal muscle to increase lean body mass and decrease body fat. The '156 Patent is directed to methods of lowering undesirably high blood serum LDL-cholesterol levels and raising blood serum HDL-cholesterol levels.

The '623 Patent stems from an application filed with the U.S. Patent and Trademark Office ("PTO") in 1989. Originally, the application included claims directed to methods of treating symptoms of diabetes as well as other conditions. The PTO issued a restriction requirement that induced the patentees to cancel all claims except those related to diabetes. The patentees then re-filed the cancelled claims in separate divisional patent applications that resulted in the '624 and '156 Patents. As a result, the specifications of the patents-in-suit are substantively identical; only the claims are different.

APPLICABLE LAW

"It is a 'bedrock principle' of patent law that 'the claims of a patent define the invention to which the patentee is entitled the right to exclude.'" *Phillips v. AWH Corp.*, 415 F.3d 1303, 1312 (Fed. Cir. 2005) (en banc) (quoting *Innova/Pure Water Inc. v. Safari Water Filtration Sys*., *Inc*., 381 F.3d 1111, 1115 (Fed. Cir. 2004)). In claim construction, courts examine the patent's intrinsic evidence to define the patented invention's scope. *See id.*; *C.R. Bard, Inc. v. U.S. Surgical Corp*., 338 F.3d 858, 861 (Fed. Cir. 2004); *Bell Atl. Network Servs*., *Inc. v. Covad Commc'ns Group*, *Inc*., 262 F.3d 1258, 1267 (Fed. Cir. 2001). This intrinsic evidence includes the claims themselves, the specification, and the prosecution history. *See Phillips*, 415 F.3d at 1314; *C.R. Bard*, 388 F.3d at 861. Courts give claim terms their ordinary and accustomed meaning as understood by one of ordinary skill in the art at the time of the invention in the context of the entire patent. *Phillips*, 415 F.3d at 1312-13; *Alloc*, *Inc. v. Int'l Trade Comm'n*, 342 F.3d 1361, 1368 (Fed. Cir. 2003).

The claims themselves provide substantial guidance in determining the meaning of particular claim terms. *Phillips*, 415 F.3d at 1314. First, a term's context in the asserted claim can be very instructive. *Id*. Other asserted or unasserted claims can also aid in determining the claim's meaning because claim terms are typically used consistently throughout the patent. *Id*. Differences among the claim terms can also assist in understanding a term's meaning. *Id*. For example, when a dependent claim adds a limitation to an independent claim, courts presume that the independent claim does not include the limitation. *Id*. at 1314-15.

"'[C]laims must be read in view of the specification, of which they are a part.'" *Id*. (quoting *Markman v. Westview Instruments, Inc.*, 52 F.3d 967, 979 (Fed. Cir. 1995) (en banc)). "[T]he specification 'is always highly relevant to the claim construction analysis. Usually, it is dispositive; it is the single best guide to the meaning of a disputed term.'" *Id*. (quoting *Vitronics Corp. v. Conceptronic, Inc.*, 90 F.3d 1576, 1582 (Fed. Cir. 1996)); *Teleflex*, *Inc. v. Ficosa N. Am. Corp.*, 299 F.3d 1313, 1325 (Fed. Cir. 2002). This is because a patentee may define his own terms, give a claim term a different meaning than the term would otherwise possess, or disclaim or disavow the claim scope. *Phillips*, 415 F.3d at 1316. In these situations, the inventor's lexicography governs. *Id*. Also, the specification also may resolve ambiguous claim terms "where the ordinary and accustomed meaning of the words used in the claims lack sufficient clarity to permit the scope of the claim to be ascertained from the words alone." *Teleflex*, 299 F.3d at 1325. But, "'[a]lthough the specification may aid the court in interpreting the meaning of disputed claim language, particular embodiments and examples appearing in the specification will not generally be read into the claims.'" *Comark Commc'ns*, *Inc*. *v*. *Harris Corp*., 156 F.3d 1182, 1187 (Fed. Cir. 1998) (quoting *Constant v.*

Advanced Micro-Devices, *Inc*., 848 F.2d 1560, 1571 (Fed. Cir. 1988)); *see Phillips*, 415 F.3d at 1323.

The prosecution history is another tool to supply the proper context for claim construction because a patent applicant may also define a term in prosecuting the patent. *Home Diagnostics, Inc., v. Lifescan, Inc*., 381 F.3d 1352, 1356 (Fed. Cir. 2004) ("As in the case of the specification, a patent applicant may define a term in prosecuting a patent."). "Like the specification, the prosecution history provides evidence of how the [patent examiner] and the inventor understood the patent." *Phillips*, 415 F.3d at 1317. Moreover, when multiple patents derive from the same initial application, the prosecution history regarding a claim limitation in any earlier patent applies with equal force to subsequently issued patents containing the same claim limitation. *Elkay Mfg. Co. v. Ebco Mfg. Co.*, 192 F.3d 973, 980 (Fed. Cir. 1999).

Although extrinsic evidence can be useful, it is "'less significant than the intrinsic record in determining the legally operative meaning of claim language.'" *Phillips*, 415 F.3d at 1317 (quoting *C.R. Bard*, 388 F.3d at 862). Technical dictionaries and treatises may help a court understand the underlying technology and the manner in which one skilled in the art might use claim terms, but technical dictionaries and treatises may provide definitions that are too broad or may not be indicative of how the term is used in the patent. *See id*. at 1318. Similarly, expert testimony may aid a court in understanding the underlying technology and determining the particular meaning of a term in the pertinent field, but an expert's conclusory, unsupported assertions as to a term's definition is entirely unhelpful to a court. *Id*. Generally, extrinsic evidence is "less reliable than the patent and its prosecution history in determining how to read claim terms." *Id*.

CONSTRUCTION OF TERMS

"About"

Neither party addressed this term in its briefs. In the parties' Patent Rule 4-5(d) Joint Claim Construction Chart, GNC identified "about" as a distinct term in certain claims from all the patents-in-suit and stated that to the extent that the term requires a definition, the Court should construe the term to mean "almost." Nutrition 21 does not ask the Court to construe the term and does not contend the term has a special meaning in the art. Because "about" is a lay term that does not require construction, the Court will not construe the term for any of the patents-in-suit.

"Administration," "administered," and "administering"

The parties agreed during oral argument that these terms, which appear in claims from each of the patents-in-suit, mean "application; to bring into use or operation into the body." The Court agrees and construes the terms accordingly for all of the patents-in-suit.

"At least about 40 days"

The parties agreed during oral argument that this term, which appears in claims from the '623 and '156 Patents, means "at least 40 days." The Court agrees and construes the term accordingly.

"Blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol"

These terms appear in claims from the '156 Patent. Neither party squarely addressed the terms in its briefs. In the Joint Claim Construction Chart, Nutrition 21 asks that the terms "be given [their] plain and ordinary meaning, *i.e.*, the amount of HDL-cholesterol in blood serum." GNC does not propose constructions for these terms, but proposes constructions of "increasing blood serum levels of HDL-cholesterol" and "undesirable low levels of blood serum HDL-cholesterol." Nutrition 21's construction will be helpful to a jury because the construction clarifies the proper relationship

between the components of the term—specifically that HDL-cholesterol is found in blood serum. Therefore the Court construes the terms to mean "amount of HDL-cholesterol in blood serum."

"Blood serum LDL-cholesterol"

This term appears in claims from the '156 Patent, and like for "blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol," Nutrition 21 asks that this term "be given its plain and ordinary meaning, *i.e.*, the amount of LDL-cholesterol in blood serum." GNC proposes no construction whatsoever. Nutrition 21's construction is appropriate for the same reason Nutrition 21's construction of "blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol" are appropriate. This is notwithstanding the fact that, unlike those previous terms, the instant term does not contain the word "level" or "levels." In all three claims where "blood serum LDL-cholesterol" is found—Claims 20, 21, and 22—the word "lowering" immediately precedes the term. Evidently, then, the claims refer to LDL cholesterol as something existing in amounts that can be altered. Nutrition 21's construction properly captures this reference. For these reasons, the Court construes "blood serum LDL-cholesterol" to mean "amount of LDL-cholesterol in blood serum."

"Blood serum lipids"

Neither party's briefs squarely address the isolated term "blood serum lipids," which appears in claims from the '156 Patent. However, in the Joint Claim Construction Chart, Nutrition 21 asks the Court to construe the term to mean "substances found in blood plasma including serum triglycerides, total cholesterol, LDL-cholesterol, and HDL-cholesterol." GNC proposes no construction. The jury may be unfamiliar with what types of substances constitute blood serum lipids, and defining the term may assist the jury.

Nutrition 21's construction is technically correct. *See* '156 Patent, cols. 3:40-41 (specifying that "[p]lasma cholesterol and triglycerides are transported in lipoproteins"), 7:29-31 (noting in reference to Example 3 that "[s]erum parameters included total cholesterol, LDL-cholesterol, HDL-cholesterol, triglycerides, apolipoprotein A_1 and apolipoprotein B"). However, the proposed construction may confuse the jury because the patent refers both to reducing "undesirable high levels of blood serum lipids" and increasing the lipid HDL-cholesterol as desired and beneficial effects of chromium administration. *See*, *e.g.*, *id*. at cols. 15:12-29 (encompassing independent Claims 1, 2, and 3, all of which are directed to methods for reducing "undesirable high levels of blood serum lipids"), 16:66-17:2 (encompassing Claim 25, directed toward a method for preventing "undesirable high levels of blood serum lipids"), and 16:8-20 (encompassing independent Claims 17 and 18, which are directed toward methods of increasing undesirable low levels of blood serum HDL-cholesterol).

Skilled artisans who read Claims 1, 2, 3, and 25 in their proper context will likely interpret those claims' methods to be directed toward reducing only those types of blood serum lipids that have undesirably high levels, not every type of blood serum lipid. *See id.* at Abstract ("The administration [of CP] is for controlling blood serum lipid levels, including the lowering of undesirably high blood serum LDL-cholesterol levels and the raising of blood serum HDL-cholesterol levels."); col. 12:19-27 (referring to beneficial results in Examples 3 and 4 and stating "[t]otal cholesterol, LDL-cholesterol and the related transport protein apolipoprotein B were decreased while apolipoprotein A_1, the HDL-cholesterol related protein, was elevated when the supplement contained [CP] . . . . each of these parameters is associated either directly or inversely to the onset of coronary artery disease . . . ."). *C.f. id.* at col. 12:49-67 (implying that "investigators"

look to total, LDL-, and HDL-cholesterol levels as predictors of coronary artery disease). Nevertheless, Nutrition 21's explicit inclusion of "HDL-cholesterol" in its construction risks confusing a lay-person jury as to CP's desired effect on HDL-cholesterol levels.

Accordingly, the Court construes "blood serum lipids" generally as "substances found in blood plasma including, for example, triglycerides, cholesterols, or apolipoproteins."

"Chromium"

The parties agreed during oral argument that this term, which appears in claims from all the patents-in-suit, means "the chromium ion portion of the chemical compound chromic tripicolinate." The Court agrees and construes the term accordingly.

"Chromic tripicolinate" and "chromic picolinate"

The parties and the Court agree that both of these terms, which appear in claims from all the patents-in-suit, are abbreviated as "CP" and mean "a chemical compound containing one chromium ion and three picolinate ions."

"Consisting essentially of"

The parties agreed during oral argument that this term, which appears in claims from the '624 and '156 Patents, means "containing no matter other than chromium picolinate that materially affects the basic and novel characteristics of the claimed method." The Court agrees and construes the term accordingly.

"Dose"

Neither party addressed this term in its briefs. However, in the Joint Claim Construction Chart, Nutrition 21 identified "dose" as a distinct term in certain claims of the '156 Patent and suggested the term means "a quantity of CP or CR" (CR presumably stands for chromium). Nevertheless, GNC does not ask the Court to construe this term. "Dose" is used according to its ordinary meaning, which the jury will be familiar with. Accordingly, the term does not require construction.

"Effective amount" and "effective dose"

1. The '623 Patent

With respect to the '623 Patent, Nutrition 21 asks the Court to construe "effective amount" and "effective dose" to mean "at least about 50 mcg. of chromium in a day."[3] GNC argues the terms should be construed to mean "amount determined to reduce hyperglycemia and stabilize serum glucose" or "200 micrograms of chromium."

Claim 1 uses "effective amount," but does not mention any dosage amount. Claim 3, which is dependent on Claim 1, specifies a method employing a dosage of "at least about 50 mcg. of chromium." *See* '623 Patent, cols. 15:21-16:2. Nutrition 21's apparent importation of that dosage amount in its proposed construction is questionable because the doctrine of claim differentiation presumes that limitations stated in a dependent claim are not part of the independent claim. *Curtiss-Wright Flow Control Corp. v. Velan*, *Inc.*, 438 F.3d 1374, 1380 (Fed. Cir. 2006). Nutrition 21

[3] On the Joint Claim Construction Chart, Nutrition 21's proposed constructions for "effective amount" and "effective dose" differ slightly: only the proposed construction for "effective amount" includes the word "about." Regardless, Nutrition 21's brief argues that both terms should be construed to mean "at least *about* 50 mcg. of chromium in a day."

argues that the specification refers to "about 50 micrograms" as the floor for the range of chromium dosages that the inventors anticipated would be effective in reducing hyperglycemia and stabilizing glucose levels. *See* '623 Patent, col. 13:24-31. Nutrition 21 also cites language from the specification that notes CP "may typically be administered on a daily basis." *Id*. at col. 13:22-23. However, the inventors' inclusion of the 50 microgram dosage in dependent Claim 3 indicates that the inventors envisioned independent Claim 1's "effective amount" to encompass something more general than a dosage of "at least about 50 micrograms of chromium," daily or otherwise. Because Nutrition 21 points to no other evidence that convincingly rebuts the claim differentiation doctrine's presumption, the Court does not adopt Nutrition 21's proposed construction of "effective amount."

The Court also rejects applying Nutrition 21's proposed construction to the term "effective dose." The term is found only in Claim 7, which reads in relevant part: "a method . . . comprising administering chromic picolinate . . . in an effective dose having at least 50 micrograms of chromium per day to an individual in need thereof." *Id*. at col. 16:13-18. Thus, adopting Nutrition 21's proposed construction of "effective dose" would render the term redundant. While not an absolute rule, all claim terms are presumed to have meaning in a claim. *Innova/Pure Water*, 381 F.3d at 1119. Nutrition 21 cites no evidence to rebut this presumption.

GNC's proposes the terms be construed as "amount determined to reduce hyperglycemia and stabilize serum glucose." However, during oral argument GNC acknowledged that potential confusion could arise from its proposed use of "determined"—specifically, it raises the question of who does the "determining." GNC offered to forego its "amount determined . . ." construction in favor of the construction "200 micrograms of chromium." According to GNC, because 200 micrograms is the only dosage that was actually administered in the studies described in the '623

Patent's specification, this was the only amount demonstrated to be effective. As such, interpreting the asserted claims to cover amounts other than 200 micrograms of chromium "would give Nutrition 21 claim coverage for quantities of chromium that the inventors did not test and for which there is no evidence or reason to believe that those amounts are effective in achieving the claimed results."[4] Additionally, GNC argues the specification itself notes that the National Academy of Sciences determined 200 micrograms of chromium to be the maximum "safe" intake amount of chromium per day. *See* '623 Patent, col. 5:36-39. GNC argues that "effective amount," and "effective dose" logically cannot exceed this maximum "safe" amount.

GNC's central argument in opposing Nutrition 21's proposed construction is that an amount or dosage stated in the construction must actually be effective and not just presumed or anticipated to be effective.[5] However, neither GNC nor Nutrition 21 support their mutual premise that "effectiveness" hinges on administration of a particular dosage in the first place. There is no evidence that the inventors envisioned the actually-administered dosage to be the only "effective amount" or "effective dose" to reduce hyperglycemia and stabilize serum glucose, or that one of ordinary skill in the art would interpret the terms to encompass only the actually-administered dosage.

Accordingly, the Court construes "effective amount," and "effective dose" to mean "amount to reduce hyperglycemia and stabilize serum glucose." This construction retains the simplistic

[4] GNC's Resp. Br. at 16-17 (Docket No. 65-1 at 22-23).

[5] GNC repeats this central argument in opposing Nutrition 21's proposed constructions of "effective lean-body[-] mass increasing amount," "effective body-fat-reducing amount," "effective[,] blood serum lipid[-]reducing amount [dose]," and "effective HDL-cholesterol increasing dose," all of which are terms in the '624 or '156 Patents. *See* GNC's Resp. Br. at 20-22, 25-26 (Docket No. 65-1 at 26-28, 32-33).

appeal of GNC's first proposed construction without requiring a "determination." Likewise, it avoids infusing specific amounts or dosages into the construction, which neither party has justified and the patent does not require.

2. The '156 Patent

With respect to the '156 Patent, Nutrition 21 argues that "effective amount" means "at least about 10 mcg. of chromium as chromic tripicolinate in a day." GNC argues that the term means "amount of chromic tripicolinate determined to increase the blood serum levels of HDL-cholesterol in the individual."[6] In supporting these respective constructions, the parties rest on their arguments with respect to the '623 Patent.[7] Those arguments—to the extent they apply to "effective amount" as the term appears in Claim 17 of the '156 Patent—are equally unconvincing here. Accordingly, for the same general reasons already stated, the Court construes "effective amount" as it appears in the '156 Patent to mean "amount to increase the blood serum levels of HDL-cholesterol in the individual."

"Effective body fat reducing amount," "effective, lean-body-mass increasing amount," "effective[,] blood serum lipid[-] reducing amount [dose]," and "effective HDL-cholesterol increasing dose"

The Court construes these terms based on the reasoning supporting its construction of "effective amount" and "effective dose." *See supra*, n.5. Accordingly, the term "effective body-fat-

[6] GNC also argues that the Court should construe "effective dose" as found in the '156 Patent to mean "effective amount" because "the normal meaning of 'dose' is 'an amount.'" GNC's Resp. Br. at 26 (Docket No. 65-1 at 32). The Court rejects this argument because the term "effective dose" does not appear in the '156 Patent.

[7] Though both parties' constructions of "effective amount" as found in the '156 Patent differ from their proposed constructions for the term as found in the '623 Patent, the parties do not address these variances. Therefore, the Court presumes the parties intend their articulated arguments with respect to the '623 Patent to apply generally to all their proposed constructions of "effective amount."

reducing amount," which appears Claim 13 of the '624 Patent, means an "amount to reduce the percentage of body fat in the mammal." The term "effective, lean-body-mass increasing amount," which appears in claims from the '624 Patent, means an "amount to increase lean body mass in the mammal." The term "effective[,] blood serum lipid[-] reducing amount [dose]," which appears in claims from the '156 Patent, means an "amount to reduce blood serum lipid levels in the individual." Finally, the term "effective HDL-cholesterol increasing dose," which appears in Claim 18 of the '156 Patent, means an "amount to increase the blood serum levels of HDL-cholesterol in the individual."

"Evaluating," "evaluation," "re[-]evaluating," and "re[-]evaluation"

Nutrition 21 argues that the Court should give these terms from the '156 Patent their "plain and ordinary meaning." In other words, Nutrition 21 argues that the Court should construe "evaluating" and "evaluation" to mean "assessing [assessment of] the condition of something" and "reevaluating" and "reevaluation" to mean "reassessing [reassessment of] the condition of something."

GNC argues that "evaluating" and "evaluation" mean "performing [performance of] medical testing to determine" the level of HDL-cholesterol, LDL-cholesterol, or blood serum lipids in either a "subject" or an "individual" and "evaluating the results thereof." GNC contends "reevaluating" and "reevaluation" in Claims 13 and 14 mean "re-performing of medical testing previously performed, evaluating the results thereof, and comparing the results of the evaluation with the re-evaluation." For Claim 19, GNC says "reevaluating" means "re-performing medical testing to determine the HDL-cholesterol level in an individual and evaluating the results thereof and comparing the results of the evaluation with the re-evaluation." For Claims 21 and 22, GNC says "reevaluating" and "reevaluation" mean "re-performing medical testing to determine the LDL-

cholesterol level in an individual and evaluating the results thereof and comparing the results of the evaluation with the results of the re-evaluation."

GNC's constructions all require "medical testing." GNC argues that medical testing is essential to determine whether one suffers from a medical condition treatable by one of the claimed methods. However, GNC cites no intrinsic or extrinsic evidence to support its contention that one of ordinary skill in the art would understand these terms to connote medical testing or that the inventors limited the scope of the term to require medical testing. Whether blood serum lipid levels may be evaluated without supervised medical tests is a fact issue and not a claim construction issue. The specification uses the root word "evaluate" only once—when specifying that the study depicted in Example 5 was performed "to evaluate the anabolic effect of chromic tripicolinate in male subjects." '156 Patent, col. 11:23-24. Although the experiment was a supervised activity that seems to have involved measurement of the subjects' body fat, this does not suggest that the inventors intended (or that skilled artisans would deem) a real-world subject's ordinary regime of CP usage to entail the same methods of laboratory measurement.[8] Moreover, the Federal Circuit cautions against limiting the claimed invention to preferred embodiments or specific examples in the specification. *Tex. Instruments*, *Inc. v. U.S. Int'l Trade Comm'n*, 805 F.2d 1558, 1563 (Fed. Cir. 1986).

Nutrition 21 argues that its constructions, which are based on the "ordinary dictionary meaning" of the root word "evaluate" simply reflect what skilled artisans would find such ordinary meaning to be. But Nutrition 21 offers no evidence to support its contention that skilled artisans

[8] The Court will not speculate as to whether the laboratory measurement methods described in the specification constitute "medical testing."

would view its chosen dictionary definition—which Nutrition 21 admits was selected from several available definitions—as a reflection of the ordinary meaning of the root word "evaluate." Therefore, Nutrition 21 does not adequately support its proposed constructions.

Although the Court does not adopt Nutrition 21's proposed constructions, the Court agrees that the '156 Patent uses the derivatives of "evaluate" in accordance with their ordinary, everyday meaning, with which the jury will be familiar. Accordingly, "evaluating," "evaluation," "reevaluating," and "reevaluation" do not require construction.

"Exercise regimen"

Nutrition 21 contends that this term, which appears in Claim 10 of the '624 Patent, means "to regularly perform physical exertion related to achieving a fitness benefit." GNC contends the term means "a regular course of strenuous bodily exertion for the sake of developing and maintaining physical fitness." The parties' proposals are relatively close except for GNC's inclusion of the adjective "strenuous." GNC argues that without including the adjective, "Nutrition 21's requested construction is so broad it could be argued that walking from one's office to the break room or even the daily removal of the cap from a bottle of chromium picolinate pills is an 'exercise regimen.'" However, Nutrition 21's construction does require that the exertion be "related to achieving a fitness benefit."

GNC provides no intrinsic support for including "strenuous" in the construction. The specification does not reference exercise at all except to note that during the experiment depicted in Example 3 the volunteers were requested not to alter their daily exercise habits and to note that the volunteers for the experiment depicted in Example 5 followed a prescribed weight lifting protocol for a total of three hours each week during the experimental period. *See* '624 Patent, cols. 6:66-68,

11:34-36. Although weight training may well be strenuous bodily exertion, GNC makes no argument, and there is no reason to believe, that the Example 5 volunteers' exertion is the type of exertion that the inventors envisioned when they adopted the claim term "exercise regimen" or that skilled artisans would limit the term to that type of exertion.

Nutrition 21's proposal expresses the term's ordinary meaning, as used in the specification. Accordingly, the Court construes "exercise regimen" to mean "to regularly perform physical exertion related to achieving a fitness benefit."

"Hyperglycemia"

In the Joint Claim Construction Chart, Nutrition 21 construes this term, which appears in Claims 1 and 7 the '623 Patent, to mean "a symptom of diabetes." GNC does not propose any construction for the term. Neither party addresses the term's construction in its briefs.

Construing the term will be helpful to the jury, who may not otherwise be familiar with the term's meaning. Further, the specification identifies hyperglycemia as a symptom of diabetes. '623 Patent, col. 1:35. Therefore, the Court construes "hyperglycemia" as "a symptom of diabetes."

"In need thereof" and "in need of"

These terms appear in several claims from all the patents-in-suit. Nutrition 21 proposes a consistent construction of the terms: "if a person administers CP, s/he is in need of CP." GNC's proposed constructions are particular to the claims in which the terms appear and are worded in reference to the methods articulated in those claims. For Claims 1 and 7 of the '623 Patent, GNC proposes construing "in need thereof" to mean "one who knows that he/she has a need to reduce hyperglycemia and stabilize serum glucose." For the '624 Patent, GNC proposes the construction "one who knows he/she has a need to increase lean body mass." For the'156 Patent, GNC proposes

the construction "one who knows he/she has a need to treat undesirable high levels of blood serum lipids." For each of the patents, the parties' dispute centers on the type of knowledge one must have, or the determination that must be made, before CP is administered. However, both parties' proposed constructions are deficient.

During prosecution, the patent examiner rejected several of the inventors' original claims under 35 U.S.C. § 112, ¶ 1 and required the addition of "in need of" and "in need thereof." Nutrition 21 notes that after the inventors' claim amendments, "the Examiner ultimately conceded the term 'in need' to cover both a 'subjective need' and an 'objective need' of a person taking CP, which is the position the inventors advocated from the beginning." *See* Sept. 1991 Amendment to U.S. Patent Application No. 07/553,184 ("Sept. 1991 Amendment") at 4-6. Nevertheless, Nutrition 21's proposed construction renders the terms meaningless because under that construction any person who "administers" CP is automatically deemed to "need" the compound. Construing the terms in this fashion ignores both the subjective and objective needs for CP referenced in the prosecution history.

GNC's argument that the ordinary meaning of "in need thereof" / "in need of" requires there to be an objective medical determination that a subject needs CP also fails. GNC argues that the language Nutrition 21 quotes from the prosecution history file indicates only what the inventors' attorneys intended when amending the patents-in-suit, not the patent examiner's understanding. However, the record before the PTO can inform the meaning of claim language because statements made during prosecution are probative of what the inventors and examiner understood claim terms to mean. *See Phillips*, 415 F.3d at 1317; *Vitrionics Corp.*, 90 F.3d at 1582. When adding the terms after the examiner's rejection of their claims, the inventors noted the examiner's finding that "'in

need thereof' / 'in need of'" encompassed a "subjective perceived need." *See* Sept. 1991 Amendment at 4-5. The examiner never challenged this contention and subsequently allowed the amended claims. No reasonable competitor reviewing and relying on this prosecution history would believe the terms do not cover an individual's subjective need for CP. *See Vitronics Corp.*, 90 F.3d at 1583 ("[C]ompetitors are entitled to review the public record, apply the established rules of claim construction, [and] ascertain the scope of the patentee's claimed invention . . . .").

The intrinsic record does not support either side's proposed constructions. In light of the prosecution history, for all the patents-in-suit the Court construes "in need thereof" and "in need of" to mean "one who has a specific perceived need."

"Increasing"

Neither party addresses this term in its briefs. In the Joint Claim Construction Chart, Nutrition 21 identifies "increasing" as a distinct term in certain claims from the '624 Patent and asks that the term "be given its plain and ordinary meaning." GNC does not ask the Court to construe this term. This term does not require construction.

"Increasing blood serum levels of HDL-cholesterol" and "increase in blood serum HDL-cholesterol"

Neither party squarely addresses these terms in its briefs. Each term appears only once—"increasing . . ." in Claim 17 of the '156 Patent and "increase in . . ." in Claim 19 of the same patent. In the Joint Claim Construction Chart, however, GNC asks the Court to construe "increasing . . ." to mean "increasing a level of blood serum lipids determined to be abnormally low," and to construe "increase in . . ." to mean "the results of the re-evaluation show an increase in HDL-

cholesterol level over that found in the evaluation." Nutrition 21 does not ask the Court to construe either term.

GNC's proposed construction for "increasing . . ." is problematic because it includes the word "determined." Additionally, the proposed construction is too broad because it refers only to an abnormally low level of blood serum lipids, whereas Claim 17 refers to the specific lipid HDL-cholesterol.

GNC's proposed construction for "increase in . . ." is unnecessary because Claim 19 dictates that CP administration be continued until "the re-evaluation indicates an increase in blood serum HDL-cholesterol." Claim 19 is a dependent claim that includes independent Claim 18's method of evaluating a subject for undesirable low levels of blood serum HDL-cholesterol and administering CP when the evaluation indicates such low levels. When interpreted in the context of Claim 18, it becomes apparent that the "increase" to which Claim 19 refers is measured in reference to the original evaluation.

Neither of GNC's proposed constructions are appropriate, and it is otherwise unnecessary to construe the terms because the Court has already construed the terms "blood serum HDL-cholesterol" and "blood serum levels of HDL-cholesterol" and has also determined that the term "increasing" (and by extension the root term "increase") does not require construction.

"Known dose"

Nutrition 21 argues that "known dose," which appears in dependent Claim 13 of the '156 Patent, means "a predetermined quantity of chromic tripicolinate or chromium." In its brief, GNC argues that the term means "an effective amount," but provides no evidentiary support for its argument, intrinsic or otherwise. In the Joint Claim Construction Chart, GNC's proposed

construction is "an amount of chromic tripicolinate determined to reduce the blood serum lipid content in the individual."

Claim 13 depends on Claim 3, which describes "[a] method for treating undesirable high levels of blood serum lipids" and includes administration of an "effective, blood serum lipid reducing dose of chromic tripicolinate." '156 Patent, col. 15:22-29. Claim 13 is directed to "[t]he method of [C]laim 3 wherein a known dose of chromic tripicolinate is administered on a plurality of days, the method additionally comprising reevaluating the level of blood serum lipids." *Id.* at col. 15:54-57. Skilled artisans would logically read the dose mentioned in Claim 13 to refer back to Claim 3's "effective, blood serum lipid reducing dose" of CP.

The Court has already construed the term "effective[,] blood serum lipid[-]reducing amount [dose]" to mean "an amount to reduce blood serum levels in the individual." Thus, GNC's chart proposal is correctly attuned to the specific function for which the doses are administered under Claim 3 and 13's methods: reduction of blood serum lipids in the individual. Moreover, GNC's chart proposal correctly acknowledges Claim 13's infusion of a knowledge element. Claim 13's use of the adjective "known" as opposed to, for example, the articles "said," "the," or "a"adds a limitation to the method of Claim 3. Unlike other terms in the '156 Patent for which GNC proposes a construction that employs the word "determined," here the adjective "known" provides intrinsic support for a predetermination of some kind.

However, GNC does not justify its implication that the patentees used "known" to mean that one must know the CP amount used will be effective. Based on the structure of the claim language, those skilled in the art would read the adjective "known" to modify the noun immediately following it: "dose." Thus, skilled artisans would read "known" to refer to quantity, not effect. Adopting

GNC's chart proposal could result in a situation where an individual administers on a plurality of days an amount of CP, without ever knowing the actual dosage she administers. The CP could be effective in reducing the individual's blood serum lipids, thus fulfilling the practice of Claim 3. But, the individual's ignorance of the specific dose would defy the practice of Claim 13.

Nutrition 21's construction—specifically its use of the words "predetermined quantity"—correctly encapsulates the relationship between the term elements "known" and "dose." However, the construction does not place the term "known dose" in its proper context within dependent Claim 13. Nutrition 21 points to no support in the claims or specification for reading "known dose" to entail administration of pure chromium in the alternative to CP. Claim 13 is specifically directed only to a "known dose of chromic tripicolinate." Nutrition 21 seems to be advocating a general construction of "known dose." But as discussed, skilled artisans would construe the dose of Claim 13 to have a very specific meaning due to the relationship between Claims 3 and 13.

Accordingly, the Court construes the term "known dose" to mean an "a dose effective to reduce blood serum lipids and whose amount is known."

"Lean body mass"

The parties agree that the term "lean body mass," which appears in several claims from the '624 Patent, means "body mass excluding the mass of body fat." The Court agrees and construes the term accordingly.

"Percentage of body fat"

This term appears in Claim 13 of the '624 Patent. GNC's proposed construction of the term as "body fat as calculated from the sum of the thickness of the triceps, subscapular and chest

skinfolds" reads a limitation into Claim 13 from the measurement protocol used in Example 5 of the specification. *See* '624 Patent, col. 11:20-43. Example 5 describes a study evaluating the anabolic effect of CP in male subjects. The study's description identifies the methodology used to measure the percentage of body fat in subjects. However, GNC cites no evidence demonstrating that persons of ordinary skill in the art would interpret "percentage of body fat" to exclusively mean a value derived from that methodology.

Likewise, GNC cites no evidence from the prosecution history that the patentees intended to limit the term to a value derived exclusively from that methodology. Conversely, Nutrition 21 cites evidence from the prosecution history that the inventors defined the percentage of body fat in terms of its inverse relationship to lean body mass; the prosecution history, in turn, cited the specification as support for that relationship. Sept. 1991 Amendment at 4; *see* '624 Patent, col. 11:39-43. The term's inclusion of the word "percentage" plainly indicates that the term refers to a portion of a greater whole. That greater whole is body mass. Therefore, the Court adopts Nutrition 21's proposed construction and construes "percentage of body fat" to mean "the percentage of body mass that excludes the lean body mass fraction."

"Plurality of days"

1. The '623 Patent

GNC's proposed construction of "plurality of days" as "at least 42 days" reads a limitation into Claim 5 from Table 3 of the specification. Table 3 summarizes the results of Example 4, a study that measured the effect of CP on subjects with adult onset diabetes. '623 Patent, col. 9:60-68. GNC argues that because one column in Table 3 has the heading "Cr Supplementation 6 Weeks," this

means that claims directed to administering CP to reduce hyperglycemia over a "plurality of days" must be deemed to refer only to a 42-day period.

GNC's argument is baseless. The Court has already noted how the Federal Circuit cautions against limiting claim term construction to examples in the specification. *Tex. Instruments*, 805 F.2d at 1563. The specification makes clear that the "description[s] of the invention [are] set forth solely to assist in understanding the invention." '623 Patent, col. 15:5-6. GNC cites no evidence to indicate that the inventors desired to limit "plurality of days" to the period during which the experiment depicted in Example 4 took place. Nor does GNC point to any evidence that one of ordinary skill in the art would construe the inventors' use of "plurality of days" to limit the envisioned period of CP administration to the period described in Example 4.

The specification does not use the term "plurality of days," and neither the specification nor any other evidentiary source refer to a specific time period for which the inventors envisioned a real-world subject would undergo CP administration. Accordingly, the Court construes the term in accordance with its ordinary meaning to one of skill in the art: "more than one day."

2. The '624 Patent

Similar to its proposed construction for the '623 Patent, GNC's argues that the Court should construe "plurality of days," as it appears in Claim 10 of the '624 Patent, to mean "at least 40 days." GNC reads in a limitation from Example 5, arguing that because the study took place over a "40-day period," claims directed to administering CP to increase lean body mass over a "plurality of days" must be deemed to refer only to a 40-day period. *See* '624 Patent, col. 11:34. Like for its proposed construction with respect to the '623 Patent, GNC cites no evidence to indicate that the inventors

desired to limit "plurality of days" to the period described in Example 5 or that skilled artisans would construe the term as limited to a 40-day period.

For the reasons articulated in construing the '623 Patent, the Court construes "plurality of days" as found in the '624 Patent to mean "more than one day."

3. The '156 Patent

Again, similar to its proposed construction for the '623 and '624 Patents, GNC argues that "plurality of days," as it appears in Claims 13, 19, and 20 of the '156 Patent, means "42 days." This time, GNC reads in a limitation from Example 3, a study that measured the effects of CP on blood serum lipid amounts. *See* '156 Patent, cols. 9:14-28, 12:4-6. GNC argues that because the study consisted of "two 42-day periods," *see id.* at col. 7:22, claims directed to administering CP to reduce blood serum lipids over a "plurality of days" must be deemed to refer only to a 42-day period. GNC cites no evidence to indicate that the inventors desired to limit the term to the period described in Example 3 or that one skilled in the art would construe the term as limited to a 42-day period.

For the reasons articulated in construing the '623 and '624 Patents, the Court construes "plurality of days" as found in the '156 Patent to mean "more than one day."

"Reducing"

Neither party addresses this term in its briefs. In the Joint Claim Construction Chart, Nutrition 21 identifies "reducing" as a distinct term in certain claims from the '623 and '624 Patents and argues that for both patents the term "should be given its plain and ordinary meaning, *i.e.*, lowering." GNC does not ask the Court to construe this term. Construction is unnecessary to aid the jury in understanding the term, and therefore the Court does not construe the term.

"Stabilizing the level of serum glucose"

This term appears in Claims 1 and 7 of the '623 Patent. Neither party addresses this term in its briefs. In the Joint Claim Construction Chart, Nutrition 21 asks the Court to construe the term as "to cause a decrease in the relative fluctuations of a human's blood sugar." GNC does not ask the Court to construe this term.

Construction of the term will aid the jury. The specification explains that glucose is blood sugar that is metabolized, that insulin dependent diabetes is a condition characterized by an inability to metabolize glucose normally, and that CP relieves undesirably high levels of glucose. *See* '623 Patent, cols. 1:46-50, 4:48-53. Therefore, the Court construes "stabilizing the level of serum glucose" to mean "to cause a decrease in the relative fluctuations of a human's blood sugar."

"Substantially pure"

This term appears in Claims 7 and 25 of the '156 Patent. The parties agreed during oral argument that the term does not require construction. The Court agrees and does not construe the term.

"Synthetic"

The parties and the Court agree that this term, which appears in Claim 1 of the '623 Patent and Claim 9 of the '156 Patent, means "outside a cell body."

"Undesirable high levels of blood serum lipids"

This term appears in certain claims from the '156 Patent. Nutrition 21 argues that the term "should be given its plain and ordinary meaning, *i.e.* an unwanted or objectionable above normal amount of blood serum lipids." Nutrition 21 bases its construction's use of the words "unwanted or objectionable" on a dictionary definition of "undesirable" and points to the specification only to

note the lack of evidence that the inventors desired to deviate from the generally-accepted meaning of "undesirable."[9] Nutrition 21 insists that it uses the dictionary definition only to indicate the generally-accepted meaning to skilled artisans, not to construe the claim term. However, Nutrition 21 cites no evidence to indicate that a skilled artisan would construe "high" to mean "above normal."

GNC argues that the term means "a level of blood serum lipids determined to be abnormally high." GNC justifies introducing "determined" into its construction by arguing that "for the serum lipid level to be classified as 'undesirable,' it must first be determined that the level is outside the desirable range." However, GNC cites no intrinsic or extrinsic evidence to support the proposition that whether a blood serum lipid level is "undesirable" requires objective determination, and the Court rejects the limitation. Moreover, similar to Nutrition 21, GNC cites no evidence to indicate that a skilled artisan would construe "undesirable high" to mean "abnormally high."

During oral argument, the Court attempted to foster the parties' compromise by proposing the construction "an unhealthy or objectionable amount of blood serum lipids," consistent with the term's plain meaning. Nutrition 21 expressed amenability to the Court's proposal but retreated from this position after GNC refused to abandon its construction. Given both sides' failure to justify their positions, the Court cannot adopt either party's proposed construction.

The Court agrees with Nutrition 21 that skilled artisans would construe "undesirable" according to its generally-accepted meaning. Indeed, the evidence does not indicate that skilled artisans would construe the term as a whole other than according to its plain meaning. As a result, the term does not need to be construed.

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[9] *See* Nutrition 21's Opening Br. at 31 (Docket No. 57-1 at 36) (citing Webster's 3d New Int'l Dictionary (1986)).

"Undesirable low level of blood serum HDL-cholesterol"

This term appears in Claim 18 of the '156 Patent. Nutrition 21 argues that its proposed construction—"unwanted or objectionable below normal amount of HDL-cholesterol"—incorporates the ordinary meaning of "undesirable low level." The Court agrees with Nutrition 21's argument that skilled artisans would construe "undesirable low level" according to its plain and ordinary meaning. But similar to before, Nutrition 21 cites no evidence to indicate that a skilled artisan would in turn construe "low" to mean "below normal."

GNC argues the term means "a level of blood serum HDL-cholesterol determined to be abnormally low," and rests on its arguments with respect to "undesirable high levels of blood serum lipids" for support. The Court again rejects those arguments.

The evidence does not indicate that skilled artisans would construe the term "undesirable low level of blood serum HDL-cholesterol" other than according to its plain meaning. Therefore, the term does not need to be construed.

CONCLUSION

For the foregoing reasons, the Court interprets the claim language in this case in the manner set forth above. For ease of reference, Appendix A sets out the claims with the terms at issue in bold, and Appendix B sets out the Court's claim constructions in table form.

So ORDERED and SIGNED this 17th day of August, 2006.

LEONARD DAVIS
UNITED STATES DISTRICT JUDGE

APPENDIX A

ASSERTED CLAIMS OF THE PATENTS-IN-SUIT CONTAINING CONSTRUED TERMS

1. United States Patent No. 5,087,623

1. A method for reducing **hyperglycemia and stabilizing the level of serum glucose** in humans comprising the **administration** of an **effective amount** of a composition comprising **synthetic chromic tripicolinate** to a human **in need thereof**.

2. The method of claim 1 wherein said **chromic tripicolinate** is in a pharmaceutically acceptable carrier and is orally ingested.

3. The method of claim 1 wherein said **chromic tripicolinate** is present in a pharmaceutically acceptable carrier in a dose having at least about 50 micrograms of **chromium**.

4. The method of claim 1 wherein said **chromic tripicolinate** is present in a pharmaceutically acceptable carrier in a dose having from about 50 to about 500 micrograms of **chromium**.

5. The method of claim 1, wherein about 200 micrograms **chromium** as of **chromic tripicolinate** are **administered** each day for **a plurality of days**.

6. The method of claim 1, wherein about 200 micrograms **chromium** as of **chromic tripicolinate** are **administered** each day for **at least about 40 days**.

7. A method for reducing **hyperglycemia** and for **stabilizing the level of serum glucose** in an individual, comprising **administering chromic picolinate**, which is substantially free of impurities from brewer's yeast, in an **effective dose** having at least 50 micrograms of **chromium** per day to an individual **in need thereof**.

8. The method of claim 7 wherein said **chromic tripicolinate** is in a pharmaceutically acceptable carrier and is orally ingested.

2. United States Patent No. 5,087,624

1. A method for **increasing** the **lean body mass** of a mammal **in need of** such increase, comprising **administering** to said mammal an **effective, lean-body-mass increasing amount** of a composition **consisting essentially of chromic tripicolinate**.

6. A method for increasing the lean body mass of a mammal **in need of** such increase, comprising **administering** to said mammal an **effective, lean-body-mass increasing amount** of **chromic tripicolinate**.

10. A method for increasing the **lean body mass** in a human **in need of** such increase, comprising **administering** an **effective lean-body-mass increasing amount** of **chromic tripicolinate** on each of a **plurality of days** in which the **human engages in an exercise regimen**.

12. A method for increasing the **lean body mass** in a human **in need of** such increase, comprising **administering** to said human an **effective lean-body-mass increasing amount** of **chromic tripicolinate** on each of a **plurality of days** in which the **human engages in an exercise regimen**.

13. A method for reducing the **percentage of body fat** of a mammal **in need of** such reduction, comprising **administering** to said mammal an **effective body-fat-reducing amount** of **chromic tripicolinate**.

3. United States Patent No. 5,175,156

1. A method for treating undesirable **high levels of blood serum lipids** in an individual **in need of** such treatment, comprising the **administration** of an **effective blood serum lipid-reducing amount** of a composition **consisting essentially of chromic tripicolinate**.

2. A method for treating undesirable **high levels of blood serum lipids** in an individual **in need of** such treatment, comprising the **administration** of an **effective, blood serum lipid reducing amount** of **chromic tripicolinate**.

3. A method for treating undesirable **high levels of blood serum lipids** in an individual, comprising:

a) evaluating the individual for undesirable **high levels of blood serum lipids**; and

b) then, when the evaluation indicates undesirable **high levels of blood serum lipids**, **administering** an **effective, blood serum lipid reducing** dose of **chromic tripicolinate**.

4. The method of claim 2 wherein said **chromic tripicolinate** is in a pharmaceutically acceptable carrier and is orally ingested.

5. The method of claim 2 wherein said **chloric tripicolinate** is present in a pharmaceutically acceptable carrier in a dose having at least about 10 micrograms of **chromium**.

6. The method of claim 2 wherein said **chromic tripicolinate** is present in a pharmaceutically acceptable carrier in a dose having from about 10 to 200 micrograms of **chromium**.

7. The method of claim 3 wherein said **chromic tripicolinate** is substantially pure.

8. The method of claim 3 wherein said **chromic tripicolinate** is substantially free of impurities from brewer's yeast.

9. The method of claim 3 wherein said **chromic tripicolinate** is **synthetic chromic tripicolinate**.

13. The method of claim 3 wherein a **known dose** of **chromic tripicolinate** is **administered** on each of a **plurality of days**, the method additionally comprising reevaluating the level of blood serum lipids.

14. The method of claim 13 wherein the **administration** of **chromic tripicolinate** is continued until re-evaluation indicates a decrease in **blood serum lipids**.

17. A method for increasing **blood serum levels of HDL-cholesterol** in an individual **in need thereof**, comprising the **administration** of an **effective amount** of **chromic tripicolinate**.

18. A method for increasing an undesirable low level of **blood serum HDL-cholesterol** in an individual, comprising:

a) evaluating the individual for the undesirable low level of **blood serum HDL-cholesterol**; and

b) then, when the evaluation indicates an undesirable low level of **blood serum HDL-cholesterol**, **administering** an **effective HDL-cholesterol** increasing **dose** of **chromic tripicolinate**.

19. The method of claim 18 wherein said does of **chromic tripicolinate** is **administered** on a **plurality of days**, the method additionally comprising re-evaluating the **blood serum HDL-cholesterol level**, the **administration** of **chromic tripicolinate** being continued until the re-evaluation indicates an increase in **blood serum HDL-cholesterol**.

20. A method for lowering **blood serum LDL-cholesterol** in an individual **in need of** such reduction, comprising the **administration**, over a **plurality of days**, of **chromic tripicolinate** in a dose having at least about 10 micrograms of **chromium** per day.

21. A method for lowering **blood serum LDL-cholesterol** in an individual **in need of** such reduction, comprising:

a) evaluating the individual's **blood serum LDL-cholesterol** level; and

b) then **administering**, over a **plurality of days**, a composition **consisting essentially of chromic tripicolinate** in a dose having at least about 10 micrograms of **chromium** per day;

c) then re-evaluating the individual's **blood serum LDL-cholesterol** level.

22. The method of claim 21 wherein the **administration** of **chromic tripicolinate** is continued until the re-evaluation indicates a decrease in **blood serum LDL-cholesterol**.

23. The method of claim 21 wherein said **chromic tripicolinate** is in a pharmaceutically acceptable carrier and is orally ingested.

25. A method for the prevention of undesirable high levels of **blood serum lipids** in a patient **in need thereof**, comprising the **administration** to said patient of substantially pure **chromic tripicolinate** in a dose having at least about 10 micrograms of **chromium** per day.

26. The method of claim 25 wherein said **chromic tripicolinate** is in a pharmaceutically acceptable carrier and is orally ingested.

30. The method of claim 1, wherein at least about 200 mcg **chromium** as **chromic tripicolinate** are **administered** each day for a **plurality of days**.

31. The method of claim 17, wherein at least about 200 mcg of **chromium** as **chromic tripicolinate** are administered each day for **at least about 40 days**.

APPENDIX B

CLAIM TERM CONSTRUCTIONS FOR THE PATENTS-IN-SUIT

1. U.S. Patent No. 5,087,623

Claim Term	Court's Construction
"about" Claims 3, 4, 5, 6	**[No construction needed]**
"administration," "administered," and "administering" Claims 1, 5, 6, 7	**[Agreed]** "Application; to bring into use or operation into the body"
"at least about 40 days" Claim 6	**[Agreed]** "At least 40 days"
"chromium" Claims 3, 4, 5, 6, 7	**[Agreed]** "The chromium ion portion of the chemical compound chromic tripicolinate"
"chromic tripicolinate" and "chromic picolinate" Claims 1, 2, 3, 4, 5, 6, 7, 8	**[Agreed]** [Abbreviated as "CP"] "A chemical compound containing one chromium ion and three picolinate ions"
"effective amount" and "effective dose" Claims 1, 7	"Amount to reduce hyperglycemia and stabilize serum glucose"
"hyperglycemia" Claims 1, 7	"A symptom of diabetes"
"in need thereof" and "in need of" Claims 1, 7	"One who has a specific perceived need"
"plurality of days" Claim 5	"More than one day"

"reducing" Claims 1, 7	**[No construction needed]**
"stabilizing the level of serum glucose" Claims 1, 7	"To cause a decrease in the relative fluctuations of a human's blood sugar**"**
"synthetic" Claim 1	"Outside a cell body"

2. U.S. Patent No. 5,087,624

Claim Term	Court's Construction
"administration," "administered," and "administering" Claims 1, 6, 10, 12, 13	**[*See* '623 Patent's construction]**
"chromic tripicolinate" and "chromic picolinate" Claims 1, 5, 6, 10, 12, 13	**[*See* '623 Patent's construction]**
"consisting essentially of" Claim 1	**[Agreed]** "Containing no matter other than chromium picolinate that materially affects the basic and novel characteristics of the claimed method"
"effective body-fat-reducing amount" Claim 13	"Amount to reduce the percentage of body fat in the mammal."
"effective, lean-body[-]mass increasing amount" Claims 1, 6, 10, 12	"Amount to increase lean body mass in the mammal."
"exercise regimen" Claim 10	"To regularly perform physical exertion related to achieving a fitness benefit"
"increasing" Claims 1, 6, 10, 12	**[No construction needed]**

"in need of" Claims 1, 6, 10, 12, 13	**[*See* '623 Patent's construction of "in need thereof," "in need of."]**
"lean body mass" Claims 1, 6, 10, 12	**[Agreed]** "Body mass excluding the mass of body fat"
"percentage of body fat" Claim 13	"The percentage of body mass that excludes the lean body mass fraction"
"plurality of days" Claim 10	"More than one day"
"reducing" Claim 13	**[*See* '623 Patent's construction]**

3. U.S. Patent No. 5,175,156

Claim Term	Court's Construction
"about" Claims 5, 6, 20, 21, 25, 30, 31	**[*See* '623 Patent's construction]**
"administration," "administered," and "administering" Claims 1, 2, 3, 13, 14, 17, 18, 19, 20, 21, 22, 25, 30, 31	**[*See* '623 Patent's construction]**
"at least about 40 days" Claim 31	**[*See* '623 Patent's construction]**
"blood serum HDL-cholesterol [level]" and "blood serum levels of HDL-cholesterol" Claims 17, 18, 19	"Amount of HDL-cholesterol in blood serum"
"blood serum LDL-cholesterol" Claims 20, 21, 22	"Amount of LDL-cholesterol in blood serum"

"blood serum lipids" Claims 1, 2, 3, 13, 14, 25	"Substances found in blood plasma including, for example, triglycerides, cholesterols, or apolipoproteins"
"chromium" Claims 5, 6, 20, 21, 25, 30, 31	**[*See* '623 Patent's construction]**
"chromium tripicolinate" and "chromium picolinate" Claims 1, 2, 3, 4, 5, 6, 7, 8, 9, 13, 14, 17, 18, 19, 20, 21, 22, 23, 25, 26, 30, 31	**[*See* '623 Patent's construction]**
"consisting essentially of" Claims 1, 21	**[*See* '624 Patent's construction]**
"dose" Claims 5, 6, 20, 21, 25,	**[No construction needed]**
"effective amount" Claim 17	"Amount to increase the blood serum levels of HDL-cholesterol in the individual"
"effective [,] blood serum lipid[-] reducing amount [dose]" Claims 1, 2, 3	"Amount to reduce blood serum lipid levels in the individual"
"effective HDL-cholesterol increasing dose" Claim 18	"Amount to increase the blood serum levels of HDL-cholesterol in the individual"
"evaluating," "evaluation," "re[-] evaluating," and "re[-]evaluation" Claims 3, 13, 14, 18, 19, 21, 22	**[No construction needed]**
"increasing blood serum levels of HDL-cholesterol" and "increase in blood serum HDL-cholesterol" Claims 17, 19	**[No construction needed]**

"in need of" and "in need thereof" Claims 1, 2, 17, 20, 21, 25	**[*See* '623 Patent's construction]**
"known dose" Claim 13	"A dose effective to reduce blood serum lipids and whose amount is known"
"plurality of days" Claims 13, 19, 20	**[*See* '623 Patent's construction]**
"substantially pure" Claims 7, 25	**[Agreed – No construction needed]**
"synthetic" Claim 9	**[*See* '623 Patent's construction]**
"undesirable high levels of blood serum lipids" Claims 1, 2, 3, 25	**[No construction needed]**
"undesirable low level of blood serum HDL-cholesterol" Claim 18	**[No construction needed]**